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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,884	01/17/2006	Keiko Shibata	648.45478X00	3701
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EXAMINER				
SASAKI, SHOGO				
ART UNIT		PAPER NUMBER		
1773				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,884

Applicant(s)

SHIBATA, KEIKO

Examiner

Shogo Sasaki

Art Unit

1773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/8/2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 2, 18, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/17/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendments to the claims are acknowledged. The new claims 19-22 are acknowledged.

Claim Interpretations

2. Regarding claim 1, the limitations "to which a methanol water mixture and a sample comprising nitropolycyclic aromatic hydrocarbons are sent," "configured to receive the methanol water mixture and the sample from the auto-sampler and configured to separate the sample comprising nitropolycyclic aromatic hydrocarbons into at least four separate nitropolycyclic aromatic hydrocarbons including 1-nitropyrene, 1,3-dinitropyrene, 1,6-dinitropyrene and 1,8-dinitropyrene" and "configured to receive the at least four separate nitropolycyclic aromatic hydrocarbons including 1-nitropyrene, 1,3-dinitropyrene, 1,6-dinitropyrene and 1,8-dinitropyrene from the separation column and to aminate the separated nitropolycyclic aromatic hydrocarbons," which are directed to the manner in which a claimed apparatus is intended to be used, do not distinguish the claimed apparatus from the prior art.

In response to page 6 to page 8, it is noted that neither the manner of operating a claimed/disclosed device nor material worked upon further structurally limit an apparatus claim. In addition, "a methanol water mixture" and "a sample" are not claimed as part of the claimed subject matter. Any further references to said elements recited were not given patentable weight even if those references further limit said unclaimed

element. Said recitations do not structurally limit the claims. It should be noted that one is not required to use the claimed device in the same manner as intended by applicant. The examiner maintains his claim interpretation.

Furthermore, the recitation "separation column configured to separate..." is interpreted to mean "separation column capable of separating..." The same applies to the reduction column. As stated in the previous actions, a C8/silica separation column specifically designed to separate a sample into four specific nitro-PAH (nitropyrene) is not disclosed in the specification. The recitation is somewhat worded in a manner that said C8 separation column specifically separates a sample into four specific nitro-PAH (Similar to claiming a stationary phase bonded with antigen X to specifically separate antibody X from other protein.). Contrary, the disclosed separation column is a silica gel anchored with C8 stationary phase. The previous office actions asserted that any hydrophobic silica gel is capable of separating compounds having different hydrophobicities (The separation principals based on the molecular polarities is the same in any C_x column).

The C8 column has been commercially available.

<http://www.sigmaaldrich.com/analytical-chromatography/analytical-products.html?TablePage=9655904>

<http://www.sigmaaldrich.com/analytical-chromatography/analytical-products.html?TablePage=17841444>

The specification does not say that the C8 column is chemically altered (e.g., bonded to other chemical moieties) to better separate the 4 nitropyrenes. The examiner maintains his position.

Specification

3. As previously presented, the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The separation column specifically designed to (structurally configured to...) separate a sample into four specific nitro-PAH lacks antecedent basis.

In response to page 7, the recitation is somewhat worded in a manner that said C8 separation column specifically separates a sample into four specific nitro-PAH (Similar to claiming a stationary phase bonded with antigen X to specifically separate antibody X from other protein.). Contrary, the disclosed separation column is a silica gel anchored with C8 stationary phase. The previous office actions asserted that any hydrophobic silica gel is capable of separating compounds having different hydrophobicities (The separation principals based on the molecular polarities is the same in any C_x column).

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The specification does not say that the C8 column is chemically altered (e.g., bonded to other chemical moieties) to better separate the 4 nitropyrenes. The examiner maintains his position.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwabuchi (IDS: JP2001-21497: Translation from Patent Abstracts of Japan provided with the last office action.) in view of Jinno (Analyst, August 1997, Vol. 122 pp787-791).

Regarding claims 1, 19 and 20, Iwabuchi discloses an apparatus for analyzing aromatic hydrocarbon comprising (Abstract; Solution; Fig. 4, Fig. 7 and "Description of Notation" in column 6; claim 2; and [0015]-[0018]):

- an auto-sampler (7: Fig. 4);
- a separation column downstream of the auto-sampler (9: Fig. 4.);

- a reduction column downstream of the separation column (17: Also see abstract provided by applicant and the figure [the Fig. 4]. These components are directly connected to one another in a fluidic sense. There are no other sample manipulating/altering means. In response to page 10 second paragraph, the sample diluted with methanol goes from the sampler 7 to column 9, the nitroarene may be eluted to the reduction column by another pump. That is not same as the sample manipulating/altering action. The chromatographic configuration stays the same in Iwabuchi's and instant application. Slight change pointed by applicant, which may or may not be present in Iwabuchi, with this configuration is obvious. Furthermore, it is noted that the analysis column of claim 2 is also taught by Iwabuchi. See element 18 in Fig. 4 and [0017]);
- temperature control tank for the reduction column (abstract; [0007]; and [0005] of instant application. Iwabuchi specifically teaches that the temperature is set higher than the room temperature [0013].);
- a fluorescence detector (20); and
- wherein the reduction column is alumina/platinum-rhodium reduction column ([0011]).

Iwabuchi does not explicitly disclose the temperature control tank for the separation column.

Jinno (Section: Effect of column temperature on PAH separation) disclose a study on the effect of column temperature for separating aromatic hydrocarbon using

C60 bonded silica. Jinno discloses that the selectivity for the separation column increases with the temperature.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a column heating/cooling means (such as the temperature control tank taught by Iwabuchi) to the separation column of Iwabuchi, for the purpose of affecting the selectivity for the silica separation column.

Manipulating the chemical nature of the column (C8 or C18) and the separation temperature is the fundamental principal of chromatography (e.g., manipulating the separation resolution and/or the band width by altering residence time, which is affected by both the column material and the separation temperature). A skilled artisan would be motivated to experiment with the column temperature (such as choosing/discovering a particular optimized temperature such as 40 degrees Celsius).

The claim would have been obvious because the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations. The claim also would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

Modified Iwabuchi does not explicitly disclose the use of C8 column. Iwabuchi uses C18 (ODS) column ([0015]). However the difference between C8 and C18 silica columns are merely in the degrees of hydrophobicities (longer branch of $(CH)_x$ -silane

versus shorter ones). The principal of the separation due to the molecular polarities are the same between the two. The C18 would have been more than capable of separating compounds as evidenced by Iwabuchi. Iwabuchi's column separates polycyclic aromatic components and nitroarene (i.e., nitro aromatic hydrocarbons, which can be monocyclic (MAH) or polycyclic (PAH): http://en.wikipedia.org/wiki/Aromatic_hydrocarbon).

Iwabuchi's analysis includes separation of di/nitropyrenes (See Fig.6; [0013] and [0020]: 1,6-dinitorrrpyrene; 1,8-dinitorrrpyrene; 1,3-dinitorrrpyrene; and 1-nitorrrpyrene). The instant application is silent to unexpected result in separating nitro PAHs due to the selection of a particular silica packing columns (Also see paragraph 4 above.).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of modified Iwabuchi and replace C18 with C8 column, since it was within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The examiner asserts that the substitution would not affect the operability of Iwabuchi's column 9. Scientist interested in studying particular carcinogenic nitro-PAH would have been motivated to experiment with various chromatography settings. This is shown by Li et al. "Determination of mono- and di-nitro polycyclic aromatic hydrocarbons by on-line reduction and high-performance liquid chromatography with chemiluminescence detection," which is provided by applicant.

Furthermore, the use of a known column material in the system of modified Iwabuchi would amount to nothing more than a use of a known packing material for a

separation column for its intended use in a known environment to accomplish an entirely expected result.

In addition, the use of C8 columns for separating nitro aromatic compounds or pyrenes was known at the time of invention. See Oehrle "J of Chromatography A, 745 (1996) 233-237" and Hammel "J of Biological Chemistry Vol 261, No. 36, (1986) pp16948-16952."

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwabuchi (IDS: JP2001-21497) in view of Jinno (Analyst, August 1997, Vol. 122 pp787-791), and in further view of Collins (US 4554132) or Anthony (US 4130474).

Regarding claim 17, modified Iwabuchi discloses all of the limitations as set forth above.

Modified Iwabuchi does not explicitly teach the ultrasonic agitation for the organic fraction extraction from the particulates.

Collins (C4/L67-C5/L13) and Anthony (Fig. 1, 14; C5/L47-52; and C7/L39-45) both teach the ultrasonic solvent extraction of solubles from solid samples.

It would have been obvious to one having ordinary skill in the art at the time of the invention to apply same technique/device taught by Collins or Anthony, for the purpose of shortening the extraction time. The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

8. Claim 1 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (Determination of mono- and di-nitro polycyclic aromatic hydrocarbons by on-line reduction and high-performance liquid chromatography with chemiluminescence detection) in view of Jinno (Analyst, August 1997, Vol. 122 pp787–791).

Regarding claims 1 and 20, Li et al. disclose an apparatus for analyzing nitropolycyclic aromatic hydrocarbon comprising (Abstract):

- a reduction column (P178/Experimental);
- heater for heating the reduction column (id. Choosing a tank among other temperature control device is obvious.);
- a separation column downstream of the reduction column; and
- a fluorescence detector ("2.2.Instrumentation," P178-179/L26-27).

As applicant pointed out, the two columns of Li are in reverse order with respect to the configuration of the apparatus in instant claims.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to reverse the order of two columns in the system taught by Li, since rearrangement of parts or the change in configuration of an invention only involves routine skill in the art.

In this case, the reduction performed prior to or after the separation does not appear to affect the analysis as long as the analyzed sample is reduced prior the detection. The examiner asserts that the reconfiguration of the columns in the system of Li would not have affected the operability of Li's system.

Li discloses that methanol is not appropriate for the detection of the separated compound (P179, column 1), but Li does not say that methanol-water mobile phase would not work with the detection (See P181, column 1, second paragraph). The portion of Li that applicant cited merely states the preference.

Li also does not explicitly disclose the temperature control tank for the separation column.

Jinno (Section: Effect of column temperature on PAH separation) disclose a study on the effect of column temperature for separating aromatic hydrocarbon using C60 bonded silica. Jinno discloses that the selectivity for the separation column increases with the temperature.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a column heating/cooling means (such as the temperature control tank taught by Iwabuchi) to the separation column of Iwabuchi, for the purpose of affecting the selectivity for the silica separation column.

Manipulating the chemical nature of the column (C8 or C18) and the separation temperature is the fundamental principal of chromatography (e.g., manipulating the separation resolution and/or the band width by altering residence time, which is affected by both the column material and the separation temperature). A skilled artisan would be motivated to experiment with the column temperature (such as choosing/discovering a particular optimized temperature such as 40 degrees Celsius).

The claim would have been obvious because the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary

skill in the art, in view of the teaching of the technique for improvement in other situations. The claim also would have been obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

Furthermore, Li does not explicitly disclose the use of auto-sampler.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to automate the loading of samples into the separation/analysis device using an auto-sampler, since providing a mechanical or automatic means to replace manual activity which accomplished the same result involves only routine skill in the art.

Modified Li further discloses that the samples containing isomers of aminated nitro polycyclic aromatic hydro carbon are separated by a C18 silica column ("2.5. Diesel exhaust sample," P179/L5-8; Fig. 2; and "2.2.Instrumentation").

Modified Li does not explicitly disclose the use of C8 column. Li uses C18 column.

However the difference between C8 and C18 silica columns are merely in the degrees of hydrophobicities (longer branch of $(CH)_x$ -silane versus shorter ones). The C18 would have been more than capable of separating compounds. The instant application is silent to unexpected result in separating nitro PAHs due to the selection of a particular silica packing columns (Also see paragraph 4 above.).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Li and replace C18 with C8 column, since it was within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. The examiner asserts that the substitution would not affect the operability of Li's separation column.

Further, the use of a known column material in the system of Li would amount to nothing more than a use of a known packing material for a separation column for its intended use in a known environment to accomplish an entirely expected result.

Modified Li further disclose that the reduction column contains platinum/rhodium catalyst ("2.3. Online reduction," P178/L1-3).

Modified Li does not explicitly disclose that platinum/rhodium catalyst is on alumina carrier. However the catalyst of Li must also have been provided on an inert carrier. Alumina and silicate, such as zeolites are well known carrier for the catalyst. Choosing from a finite number of possible solutions is obvious.

It would have been obvious to one having ordinary skill in the art at the time of the invention to choose alumina as an inert support for the catalyst, since it was within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use.

Further, the use of a known inert carrier such as alumina in the system of Li. would amount to nothing more than a use of a known carrier for a metallic catalyst for its intended use in a known environment to accomplish an entirely expected result.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (Determination of mono- and di-nitro polycyclic aromatic hydrocarbons by on-line reduction and high-performance liquid chromatography with chemiluminescence detection) in view of Jinno (Analyst, August 1997, Vol. 122 pp787-791), and in further view of Collins (US 4554132) or Anthony (US 4130474).

Regarding claim 17, modified Li discloses all of the limitations as set forth above.

Modified Li does not explicitly teach the ultrasonic agitation for the organic fraction extraction from the particulates.

Collins (C4/L67-C5/L13) and Anthony (Fig. 1, 14; C5/L47-52; and C7/L39-45) both teach the ultrasonic solvent extraction of solubles from solid samples.

It would have been obvious to one having ordinary skill in the art at the time of the invention to apply same technique/device taught by Collins or Anthony, for the purpose of shortening the extraction time. The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art.

Response to Arguments

10. Applicant's arguments filed 2/8/2011 have been fully considered.

11. In response to page 6 to page 7 regarding the claim interpretations, it is noted that neither the manner of operating a claimed/disclosed device nor material worked upon further structurally limit an apparatus claim. The examiner has already responded

to said arguments which are substantially identical to the one filed 8/20/09; 11//30/09; and 5/25/10. The examiner maintains his previous position.

12. In response to page 7, second paragraph, the examiner maintains the objection to the specification. The examiner has already responded to said arguments previously.

13. Applicant's arguments with respect to the prior art rejections have been considered but are not persuasive.

The much of the arguments are substantially identical to the arguments provided in the reply filed on 5/25/2010. The examiner has already responded to these arguments. The examiner will only address new arguments.

In response to page 14 regarding the rejection of claim 17, Collins (C4/L67-C5/L13) and Anthony (Fig. 1, 14; C5/L47-52; and C7/L39-45) both teach the ultrasonic solvent extraction of solubles from solid samples. The arts are analogues to the one in claim 17. The claim would have been obvious to one having ordinary skill in the art at the time of the invention. The examiner asserts that a skilled artisan would have been motivated to apply the same technique/device taught by Collins or Anthony, for the purpose of enhancing the extraction.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian R Gordon/

Primary Examiner, Art Unit 1773